

**REMARKS**

The present invention relates in part to assay devices comprising elements for the controlled flow, delivery, incubation, separation, washing and other steps of the assay process. The devices of the present invention can provide advantageous capture efficiencies and sensitivities for the assay of plurality of target molecules.

Claims 74-84 and 92-100 are presently pending. Amended claims 74 and 92 find basis in the specification as filed, for example at page 25, lines 22-29. The amended claims are commensurate in scope with the claims as previously filed, and are offered solely to assist the examiner in understanding the instant application. No new matter is introduced.

Notwithstanding the foregoing, Applicant expressly reserves the right to pursue subject matter no longer claimed in the instant application in one or more applications that may claim priority hereto.

Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

*Non-Art Based Remarks*1. 35 U.S.C. § 112, Second Paragraph (definiteness)

Applicant respectfully traverses the rejection of claims 83 and 84 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. According the Examiner words, "[t]hese claims are confusing [as to] what structures are contemplated to achieve the 'capillary space' because no second surface is claimed." Office Action mailed April 14, 2005, page 2. Applicant submits that this assertion is in error. Furthermore, Applicant submits that the claims meet the requirement under 35 U.S.C. §112, second paragraph, to define the claimed subject matter with reasonable particularity. .

As an initial matter, it is noted that the now-rejected claims were previously indicated to be allowable by this Examiner. Prosecution has been reopened by Applicant's filing of a supplemental Information Disclosure Statement, accompanied by a Request for Continued Examination so that a reference may be considered. Applicant respectfully submits that this previous allowance of the claims is at odds with the Examiner's current definiteness rejection.

Patent  
071949-1307

Moreover, while the Examiner asserts that the claims do not disclose the structures forming the recited capillary space, this is demonstrably incorrect. Claim 83 explicitly recites that a capillary space is formed between a nonporous surface and a second surface spaced at a capillary forming distance from that nonporous surface. Claim 84 explicitly recites that the nonporous surface is not part of a capillary space.

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed.Cir.1994). See also *Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed.Cir.1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more"). Rejected claims 83 and 84 meet this standard, a fact previously acknowledged in the Examiner's allowance of these claims.

In view of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

*Art-Based Remarks*

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 74-81 and 92-99 under 35 U.S.C. §102(b), as allegedly being anticipated by Stöcker, U.S. Patent 4,647,543 ("the '543 patent").

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also MPEP §2131.

The Examiner's characterization of the reference and its relationship to the claimed invention is not entirely clear. As best as Applicant can determine, the Examiner appears to be analogizing the supports of Stöcker to particles in Applicant's claim ("Support 1(a) has been read on the claimed particles that immobilize the sample."; Office Action mailed April 14, 2005, page 2). However, Applicant's claim does not recite that particles immobilize sample. Rather, in certain claimed embodiments, particles comprising receptors that bind one or more of a plurality of target ligands are immobilized to discrete zones on a non-porous surface. See, e.g., claim 74.

Patent  
071949-1307

The Examiner has not indicated which features of the Stöcker patent reference meet these various characteristics. This failure to properly consider and address the language of the present claims cannot establish a *prima facie* case of anticipation.

Moreover, the samples in Stöcker which the Examiner alleges are “particles” are actually fragments of a microscope slide cover slip that has been scored and broken into fragments. ‘543 patent, column 9, lines 36-39. The ‘543 patent discloses that relatively large (5 mm x 5 mm) frozen tissue specimens are mounted on standard cover slips which are then subdivided into fragments for attachment to a support. The Examiner has not indicated how it is believed the skilled artisan would consider such cover slip fragments to be “particles” as the Examiner asserts, particularly as that term is used in light of the present specification.

Nevertheless, in an effort to advance prosecution, Applicant has amended independent claims 74 and 92 herein to refer to particles having a size range from 1 nm to 5  $\mu$ m. In contrast, the glass supports disclosed in the ‘543 patent are about 2 to 3 orders of magnitude larger in size to accommodate the large specimens and the physical nature of the manipulations employed in the ‘543 patent. *See, e.g.*, ‘543 patent, column 7, lines 37-39 and 49-50; see also column 7, lines 64-65, which indicate that even a “miniature frozen section” is on the order of 0.5 mm x 0.5 mm, *i.e.*, once a 5 mm x 5 mm frozen section has been divided into 100 portions.

Because the ‘543 patent does not disclose every limitation of the claimed invention, no *prima facie* case of anticipation has been established. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) be reconsidered and withdrawn.

### 35 U.S.C. § 103

Applicant respectfully traverses the rejection of claims 82 and 100 under 35 U.S.C. § 103(a) as allegedly being obviousness over the Stöcker ‘543 patent.

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited references or in knowledge available to the ordinarily skilled artisan, to modify or combine the references; there must be a reasonable

expectation of success in combining the references; and the references must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) *See also*, MPEP §2143.

The Examiner asserts that the only deficiency between the '543 patent and present claims 82 and 100 is the choice of materials from which the "particles" (the Examiner's characterization) are made; that the '543 patent is silent on the composition of "particles"; and that the use of latex, zirconia, alumina, titanium, etc., would be obvious based on "their long track record of use with immunological materials." Office Action mailed April 14, 2005, page 3. Applicant respectfully disagrees with these assertions.

The '543 patent is not silent on the composition of the supports used to immobilize tissue samples, which the Examiner apparently believes equate to the "particles" of the present claims. In fact, the supports in all cases in the '543 patent are made of glass from conventional microscope coverslips. These glass "cover slip" fragments ("supports" by Stöcker) are used so that a tissue sample may be emplaced on a large support, and the support then divided into smaller fragments. *See, e.g.*, '543 patent, claims. As mentioned above, the underlying rejection for anticipation over Stöcker fails to indicate how the skilled artisan would consider such cover slip fragments to be "particles" as the Examiner asserts, particularly as that term is used in light of the present specification.

Additionally, the Examiner's assertion that the claimed particle types (latex, zirconia, alumina, titanium, etc.) would be obvious because they have a "long track record of use with immunological materials" is an entirely unsupported assertion. Applicant requests that the Examiner comply with MPEP 2144.03(C) by providing evidence to support this assertion. Furthermore, nothing of record indicates that such materials would be dividable in the manner that the glass supports disclosed in the '543 patent are used.

Finally, as discussed above in response to the anticipation rejection based on the '543 patent, Applicant has amended independent claims 74 and 92 herein to refer to particles having a size range from 1 nm to 5  $\mu$ m. In contrast, the glass supports disclosed in the '543 patent are about 2 to 3 orders of magnitude larger in size to accommodate the large specimens and the physical nature of the manipulations employed in the '543 patent. Nothing of record even

Patent  
071949-1307

suggests that the minutely sized particles of the present claims either could or should be employed in the manner disclosed for the supports in the '543 patent.

Because the '543 patent does not teach or suggest the instantly claimed invention, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, and respectfully requests that the rejection be reconsidered and withdrawn.

### CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,

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